

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MARYLAND**

AMERICAN ACADEMY OF PEDIATRICS, *et al.*,

Plaintiffs,

v.

FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants.

Civ. Action No. 8:18-cv-883-PWG

**PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT**

Plaintiffs move pursuant to Federal Rule of Civil Procedure 56 for the Court to grant summary judgment in their favor, to vacate the challenged “Guidance for Industry,” issued by the Food and Drug Administration (“FDA”) in August 2017, and to enter an order awarding appropriate equitable relief. As explained in the accompanying standard of review and memorandum, the Guidance is subject to vacatur for three independent reasons. First, the Guidance authorizes the continued marketing of newly deemed tobacco products such as e-cigarettes and cigars without the required FDA marketing order; it is therefore contrary to federal law requiring FDA to conduct premarket review of all new tobacco products. *See* 21 U.S.C. § 387j; 5 U.S.C. § 706; *see also* U.S. Const. art. II, § 3. Second, FDA issued the Guidance without giving the public prior notice and an opportunity to comment, in violation of the rulemaking requirements of the Administrative Procedure Act. *See* 5 U.S.C. §§ 553, 706. Finally, the Guidance is arbitrary and capricious because, among other reasons, FDA provided no meaningful contemporaneous justification of its decision to suspend premarket review and did not account for a major aspect of that decision—the costs to public health from unreviewed new tobacco products continuing to be marketed, particularly to children. *See id.* § 706.

Dated: July 10, 2018

Respectfully submitted,

/s/ Kelly P. Dunbar

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